AESTHETIC UPDATE

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Treatment of Acne Scars of Skin Types II to V by Sublative Fractional Bipolar Radiofrequency and Bipolar Radiofrequency Combined with Diode Laser

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Abstract

Objective: This study evaluated the safety and efficacy of sublative fractional bipolar radiofrequency and bipolar radio frequency combined with diode laser for the treatment of both superficial and deep acne scars in patients with skin types II to V. **Design:** Prospective, single-center study. Subjects received up to five treatments with sublative fractional bipolar radiofrequency and bipolar radiofrequency combined with diode laser. Treatments were directed to at least two facial (forehead, perioral, cheeks) and/or neck areas with acne scars at four-week intervals. Treatment parameters on each subject were based on skin type and on skin responses to test spots on the target area just before treatment. **Setting:** Physician office.

Participants: Subjects (n=20, aged 40.7±10.5 years [mean ± SD], skin

types II-V) with acne scars and without acne lesions enrolled in this prospective study. Measurements: Results were evaluated just before each treatment and at four and 12 weeks after the final treatment using the Goodman Scar Scale, a quantitative method of evaluating scars that attempts to reduce grading subjectivity, as well as by patient satisfaction. Results: Acne scars improved significantly one month after three treatments and improvement persisted for at least 12 weeks after the fifth treatment. Improvement was not affected by skin type. Adverse effects were limited to transient ervthema and edema. **Conclusion:** The combination of diode laser and bipolar radiofrequency energy device in addition to fractionated sublative radiofrequency is a safe and statistically significantly effective

combined modality for the treatment of both superficial and deep acne scars in patients with skin types II to V with minimal downtime and no significant side effects.

Introduction

Acne scars have multiple morphologies1 and often require different technical approaches to achieve an optimal cosmetic outcome, especially in dark-skinned subjects.² Acne scars are commonly classified as ice pick, rolling, or boxcar.1 Ice pick scars have traditionally been treated by punch excision, subcision, or chemical reconstruction of skin scars (CROSS) technique with 100% trichloroacetic acid³; rolling scars by subcision and/or laser resurfacing: boxcar scars by punch elevation, subcision, and/or laser resurfacing; deep boxcar scars by punch excision; and shallow boxcar scars by laser resurfacing. Combinations of modalities may also be required.4

Dermabrasion is very effective in the treatment of scars, but is not widely used due to blood spattering and the need for a high skill level to produce excellent results. Chemical peels, which are most effective against macular scars,⁵ are associated with variable levels of improvement. Biomaterials such as collagen. hyaluronic acid (HA), autologous fat, or other fillers offer transient improvement, 4,6-8 but are often used for focal rolling scars. Subdermal minimal surgery has recently been introduced,9 which is performed by pneumatically accelerating a carrier fluid jet containing high-mass molecules of HA. These molecules then disperse into the skin under the targeted scar.

For the past 10 years, the mainstays of acne scarring therapy have been nonablative and ablative lasers. Newer fractional technologies



have advanced the treatment of acne scarring significantly, as they are able to reach the dermal layer yet have a relatively low side-effect profile. These technologies may even be used safely in dark skin.2 Laser procedures are effective against boxcar scars and rolling scars. 5 The ablative devices, such as the CO₂ and erbium-doped yttrium aluminium garnet (Er:YAG) lasers,10 are effective, but may be associated with long recovery times and side effects including postinflammatory hyperpigmentation. They can, however, be used successfully in dark skin.11

Nonablative devices include the neodymium-doped yttrium aluminium garnet (Nd:YAG) and diode lasers, long-pulsed 1450nm diode, the 1320 and 1064nm Nd:YAG, and 1540nm erbium glass lasers, 5,12 although careful attention must be paid to parameters in Asian skin types. 13 Although side effects and recovery times with nonablative lasers are reduced compared to ablative lasers, multiple treatments are required to reach significant efficacy. Examples include the 1550nm fractional erbium-doped laser¹⁴⁻¹⁶ and the 1540nm fractional laser.17

Recent reports have presented objective evidence of the efficacy of devices that combine ablative with nonablative fractional technology for the treatment of acne scars. 18-23 A relatively new modality uses fractionated bipolar radiofrequency (RF) energy, which has been shown to improve mild rhytids, skin texture, smoothing, and tightening. 24,25 This treatment—sublative rejuvenation (SR)—provides a coagulative (nonablative) effect limited to the mid-dermis in addition to an ablative injury to less than five percent of the epidermis. The advantages of this modality are reduced down time, lack of interaction with melanin, and low

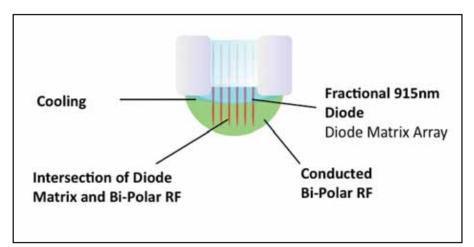


Figure 1. Schematic of Combination Bipolar Matrix Array and Bi-Polar RF (DLRF). The intersection of the two modalities creates thermal bands at 1.5mm into the dermis causing collagen contraction. Figure courtesy of Syneron Medical LTD.

side-effect profile. One prior evaluation with similar technology has been published for acne scars.²⁶

The current article seeks to ascertain the efficacy and safety of SR in addition to a diode laser/bipolar RF (DLRF) energy for the treatment of both superficial and deep acne scars in skin types II to V.

Methods

Subjects. Healthy men and women (n=20, 8 men/12 women, aged 40.7 ± 10.5 years [mean \pm SD], skin types II–V) with acne scars successfully enrolled in the study. All female subjects were postmenopausal, surgically sterilized, or used an acceptable form of birth control for at least three months before the study began. All subjects provided signed informed consent. Exclusion criteria were active acne; pregnancy; breastfeeding; active electrical implant; permanent facial implant; injectable filler in area to be treated within nine months of investigation; surgical, chemical, or light-based facial treatments in the past six months; isotretinoin treatment within six

months; immunosuppression; currently tanned or unable to refrain from tanning within the investigation period; or any dermatological, hormonal, or medical condition (or history) or therapy that might compromise a subject's safety or interfere with interpretation of the study results.

Treatment device. Treatment of acne scars consisted of irradiation with a combination of biopolar RF and 915nm diode laser energy (Matrix IR, Syneron Medical Ltd., Yokneam, Israel) (DLRF) followed by sublative bipolar RF energy (Matrix RF, Syneron)(SR). Both applicator handpieces derived energy from a common platform (eLaser, Syneron).

The DLRF device was designed to create a focal coagulation of tissue at approximately 1.5mm skin depth to stimulate collagenesis (Figure 1), thereby elevating the deeper area of the scar.²⁷ The SR energy enters the dermis through ablation caused by rows of electrode pins on the square disposable tip (Figure 2). The nonablative dermal heating is a combination of coagulative damage

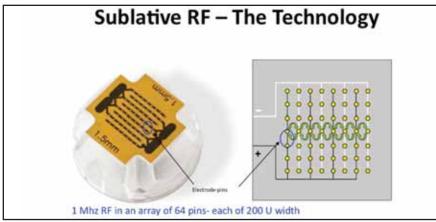


Figure 2. Sublative Rejuvenation Disposable Tips and Schematic. Radiofrequency current flows between the positive and negative mini-electrodes. Control of this current allows varying degrees of tissue impact. In the space of no current flow a healing reservoir is obtained. Image courtesy of Syneron Medical LTD.

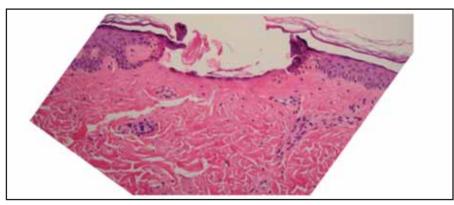


Figure 3. Photomicrograph of skin wound taken immediately after sublative rejuvenation pulse. Note clean ablation of epidermis and upper dermis with slight coagulation of the upper dermis. Photomicrograph courtesy of Syneron Medical LTD.

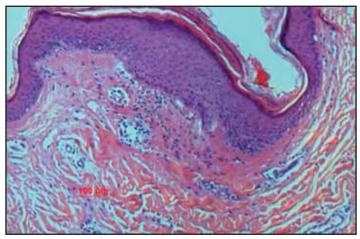


Figure 4. Thirty-six hours after treatment, note crust formation and deep dermal coagulation and remodeling. Reprinted with permission from: Hruza G, et al. Skin rejuvenation and wrinkle reduction using a fractional radiofrequency system. *J Drugs Dermatol*. 2009;8(3): 259–265.

and a subcoagulative heat effect (Figure 3), causing dermal remodeling. DLRF was included in this study because the authors hypothesized that this could be beneficial in treating ice pick scars due to the device design since these types of scars have proven particularly difficult to treat²⁸ and many individuals presenting for treatment of acne scarring have multiple types of scarring (i.e., rolling, ice pick, boxcar).

Study design. In this prospective study, subjects with acne scars received up to five treatments in at least two facial (or neck) areas at four-week intervals. Areas treated included the cheeks, forehead, perioral, and neck. Target areas were washed with mild soap and water before DLRF treatment. After a layer of conductive gel was applied to the target areas, subjects received 3 to 4 lesional passes. Treatment parameters on each subject were based on skin type and skin responses to test spots on the target area just before treatment, with clinical endpoints being erythema and edema. DLRF laser fluence ranged from 40 to 85J/cm² and RF fluence ranged from 50 to 100J/cm³. No anesthetic was used for this portion of the treatment. When DLRF treatment was completed, the conductive gel was removed and the treated areas were allowed to cool at room temperature for 30 minutes, after which topical anesthesia (prilocaine [7%] and lidocaine [7%]) was applied for 30 minutes. The skin was then cleansed with acetone, alcohol, and water; patted dry; and left to air dry for 10 minutes. These areas were then treated with SR with fluence (17–25J/cm³/pin) determined by skin response to a test spot. Epidermal ablation was five percent in each area treated, with dermal coagulation area

directly proportional to the energy of the RF (Figure 4).

Post-treatment care consisted of application of petrolatum and sunscreen. Subjects were instructed to avoid exfoliants, to not excoriate healing lesions, to avoid tanning salons and sun, and to use sunscreen (sun protection factor [SPF 30]) during the entire study period.

Evaluation of results. Efficacy and adverse effects were assessed by physical examination at each treatment visit and at the 4- and 12-week follow-up visits. The evaluation was one month after treatment three and immediately before treatment four. Other assessments were made as shown in Table 1. Scars were evaluated at each time point using the scale in Table 2. Differences were evaluated for significance by Friedman's test, the Wilcoxon Signed-Rank test, the Mann-Whitney test, and Pearson's chi square test.

Results

Scar and scar texture scores.

Scars. Scars on the cheeks, perioral area, forehead, and neck were assessed at each visit according to the scale in Table 2. Scores of the four anatomical areas were combined for non-parametric statistical analysis. The median scar assessment scores at each visit are shown in Table 3. A graph of the scar scores is presented in Figure 5.

Friedman's test (a nonparametric equivalent to the repeated measures analysis of variance) for the treatment 1 (T1) through T5, four-week follow-up, and 12-week follow-up visit groups showed that the median scar assessments among the seven groups differed significantly (p<0.0001). Friedman's test, however, does not specify which among the six non-baseline groups differs significantly from baseline (T1). Wilcoxon Signed-

| TABLE 1. Study protocol | | | | | | | |
|---------------------------------------|-------|----|----|----|----|---------------------|----------------------|
| EVALUATION TOOL | VISIT | | | | | | |
| | T1 | T2 | Т3 | T4 | T5 | 4-WEEK FOLLOW UP | 12-WEEK FOLLOW UP |
| *Photography | Х | Х | х | Х | Х | Х | х |
| *Assessment of scars and texture | х | х | х | х | Х | Х | Х |
| †Comfort during treatment | Х | Х | х | Х | Х | | |
| *Subject satisfaction, improvement | | | х | | Х | Х | х |
| Adverse events | Х | Х | Х | Х | Х | х | х |

*Before treatment; †After treatment; T=treatment

| TABLE 2. | Global | acne | scarring | classification29 |
|----------|--------|------|----------|------------------|
|----------|--------|------|----------|------------------|

| (GRADE) TYPE | NUMBER OF LESIONS 1 (1–10) | NUMBER OF LESIONS 2 (11-0) | NUMBER OF LESIONS 3 (>20) |
|---|----------------------------------|----------------------------------|---------------------------------------|
| (A) Milder scarring (1 point each)Macular erythematous or pigmentedMildly atrophic dish-like | 1 point | 2 points | 3 points |
| (B) Moderate scarring (2 points each) Moderately atrophic dish-like Punched out with shallow bases small scars (< 5mm) Shallow but broad atrophic areas | 2 points | 4 points | 6 points |
| (C) Severe scarring (3 points each) Punched out with deep but normal bases, small scars (< 5mm) Punched out with deep abnormal bases, small scars (<5 mm) Linear or troughed dermal scarring Deep, broad atrophic areas | 3 points | 6 points | 9 points |
| (D) Hyperplastic papular scars | 2 points | 4 points | 6 points |
| (D) Hyperplastic keloidal, hypertrophic scars | Area <5cm² 6 points | Area 5–20 cm² 12 points | Area >20 cm ² 18 points |

Reproduced with permission from Goodman GJ, Baron JA. Postacne scarring—a quantitative global scarring grading system. *J Cosmet Dermatol.* 2006;5(1):48–52.²⁹

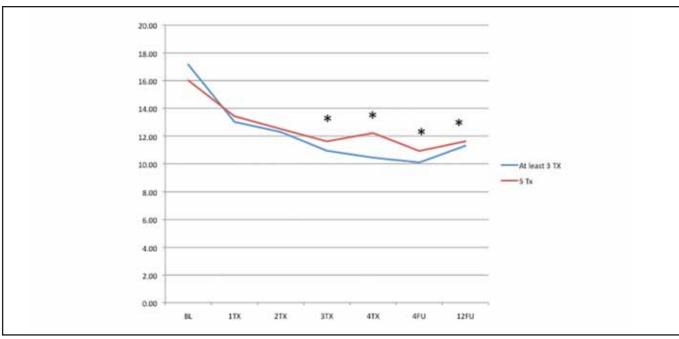


Figure 5. Average Goodman Scar Score Over Time. Patients with at least three treatments versus patients with five treatments. *=statistical significance.

| TABLE 3. Median (IQR) scar scores (cheek, perioral, forehead, neck) at each visit | | | | | |
|--|------------|-----------------|--|--|--|
| VISIT | SCAR SCORE | <i>P</i> VALUE* | | | |
| Т1 | 15.0 (8.3) | _ | | | |
| T2 | 11.0 (6.0) | 0.0775 (ns) | | | |
| Т3 | 11.0 (6.7) | 0.0100 (ns) | | | |
| T4 | 9.0 (5.7) | 0.0002 (s) | | | |
| Т5 | 9.5 (6.3) | <0.0001 (s) | | | |
| 4-WEEK FOLLOW UP | 9.5 (4.6) | <0.0001 (s) | | | |
| 12-WEEK FOLLOW UP | 9.0 (6.0) | 0.0001 (s) | | | |
| IQR=interquartile range, a measure of dispersion; T=treatment; s=significant; ns=not significant *Compared with baseline (T1), Wilcoxon Signed-Rank test | | | | | |

Rank comparisons of each treatment group with baseline (T1) revealed treatment groups in which the median scar assessment score differed

significantly from baseline. The pvalues are presented in Table 3.

The data show that the median scar scores at the T4, T5, four-week

follow-up, and 12-week follow-up visits were significantly lower than the median scar score at baseline. Since six comparisons with baseline were made, the Bonferroni correction was applied to obtain the appropriate cutoff level. The traditional level (p=0.05) was adjusted by dividing 0.05 by six, the number of comparisons with baseline. With the new p=0.0083 cutoff level, the median scar scores of only the four previously mentioned groups differed significantly from baseline.

The effect of skin type on improvement in scar assessment scores at 12 weeks compared to baseline was evaluated by the Mann-Whitney test. Data were divided into two categories: Skin types II through III and skin types IV through VI. The analysis showed that the median scores of the two groups did not differ significantly (p=0.9758), indicating that the scar assessment scores are not affected by skin type. Early in the



| TABLE 4. Distribution of subjects among rough and regular scar texture groups and comparison with baseline (T1) | | | | | | | |
|---|-------|-----------------------|-----------------------|----------------------|-----------------------|---------------------|-----------------------|
| TEXTURE | VISIT | | | | | | |
| | T1 | T2 | Т3 | T4 | T5 | 4-WEEK FOLLOW UP | 12-WEEK FOLLOW UP |
| ROUGH | 19 | 13 | 12 | 7 | 1 | 2 | 1 |
| REGULAR | 8 | 14 | 15 | 20 | 23 | 22 | 24 |
| <i>P</i> VALUE | | <i>p</i> =0.0966 (ns) | <i>p</i> =0.0541 (ns) | <i>p</i> =0.0011 (s) | <i>p</i> =<0.0001 (s) | p=<0.0001 (s) | <i>p</i> =<0.0001 (s) |
| T=treatment; s=significant; ns=not significant | | | | | | | |

study it appeared that people with darker skin types were getting better results than Caucasians (Figure 6), but this difference did not persist after the treatments were completed. Clinical examples of patients after treatment series are presented in Figures 7, 8, and 9.

Scar texture. Pearson's chi square test was used to evaluate scar texture because texture consisted only of two groups—rough and regular. The comparative data are presented in Table 4.

The analyses show that the proportions of scar texture scores at the T4 (1 month after the 3rd treatment and just before the 4th treatment), T5, four-week follow-up, and 12-week follow-up visits all differed significantly from baseline (T1). The data indicate that texture improves for more subjects with continued treatment up to T5, in which all but one subject achieved regular texture, and that the effects persist for at least 12 weeks after T5 in nearly all subjects.

Subject grading. Subjects graded acne scars, skin texture, coloration, and

overall improvement at T3, T5, four weeks, and 12 weeks, using the following scale: 0=no improvement, worsening; 1=slight improvement; 2=moderate improvement; 3=good improvement; 4=excellent improvement.

For acne scars, at least moderate improvement was achieved by 50 percent of subjects at T3, 75 percent of subjects at T5, 58 percent of subjects at four weeks, and 63 percent of subjects at 12 weeks. These data suggest a trend toward maximum improvement in acne scars at T5 and persistence of the improvement in most subjects for at least 12 weeks. For skin texture, at least moderate improvement was achieved by 60 percent of subjects at T3, 62 percent of subjects at T5, 68 percent of subjects at four weeks, and 60 percent of subjects at 12 weeks.

For coloration, at least moderate improvement was achieved by 43 percent of subjects at T3, 46 percent of subjects at T5, 58 percent of subjects at four weeks, and 58 percent of subjects at 12 weeks. These data suggest a trend toward maximum

improvement in coloration at four weeks and persistence of this level of improvement in most subjects for at least an additional eight weeks. For overall improvement, at least moderate improvement was achieved by 50 percent of subjects at T3, 69 percent of subjects at T5, 58 percent of subjects at four weeks, and 62 percent of subjects at 12 weeks. These data suggest a trend toward maximum overall improvement at T5 and persistence of the improvement in most subjects for at least 12 weeks.

Subject satisfaction. Subject satisfaction with the treatment and results was evaluated at T3, T5, four weeks, and 12 weeks. Subject responses included "not satisfied," "somewhat satisfied," "satisfied," "very satisfied," or "extremely satisfied." The percentage of responses of "satisfied" or better, however, was 55 percent at T3, 69 percent at T5, 58 percent at four weeks, and 50 percent at 12 weeks, suggesting a trend toward peak satisfaction at T5, which may begin to decline at four and 12 weeks

Tolerance. Discomfort during

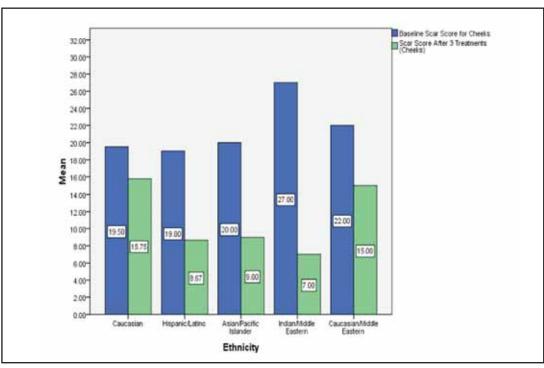


Figure 6. The mean acne score for each ethnicity at baseline is compared to the mean acne scar for each ethnicity one month after completing three treatments. The number of patients in each ethnicity group was Caucasian=10, Hispanic/Latino=4, Asian/Pacific Islander=3, Indian/Middle Eastern=2, and Caucasian and Middle Eastern (she is Fitzgerald skin type III)=1.

treatment was evaluated for each modality (DLRF and SR) at each treatment visit using a 5-point scale in which 0=no pain and 4=maximum tolerable pain. Data were evaluated by nonparametric statistics. Median pain scores were usually higher during DLRF treatment than during SR treatment. The median pain scores for DLRF decreased from 2.6 for treatment 1 and to 1.75 for treatment 5. The median scores for SR decreased from 1.55 to 0.75 from treatment 1 to 5.

Side effects and complications.

Crust formation and shedding. The duration of the appearance and shedding of treatment-induced crusts was recorded at each treatment visit. Crusts on average appeared within 1 to 2 days after treatment and were

shed by 3 to 4 days. Subjects were able to apply makeup effectively on Days 2 to 3.

Edema and erythema. Edema was noted in almost all patients and resolved in 1 to 3 days. Erythema was observed in all patients and resolved within 1 to 2 days. Post-inflammatory hyperpigmentation occurred in one patient with skin type IV but resolved after the next treatment without intervention other than reminding the patient to use sunscreen. No ulcerations, scars, infections, or prolonged or delayed evidence of hyper or hypopigmentation was noted in any patient.

Discussion

To the authors' knowledge, this is the first study to evaluate the

combination of diode laser and fractional bipolar RF with sublative fractionated RF for the treatment of acne scars. Ramesh et al²⁶ treated acne scars of 30 subjects (skin types IV-VI) with a Matrix tunable RF device similar to the RF device used in the present study. All subjects were pretreated with oral antibiotics and the acne scars of eight subjects were subjected to subcision before RF treatment. Subjects received up to four treatments at one-month intervals. Adverse effects included a transient burning sensation, edema, and erythema. Crusting was observed on the treated areas. Improvement ranged from 10 to 50 percent at two months and from 20 to 70 percent at six months. Improvement in this study was based on comparison of





Figure 7. Hispanic study patient before and one month after three treatments of SR and DLRF



Figure 8. Same patient as Figure 7, opposite cheek view. Hispanic patient before and one month after three treatments

photographs by two independent observers using a visual analog scale. Subcision appeared to enhance outcomes as reported by patients who had undergone subcision versus patients who had not.

Bipolar RF with a diode laser has been used for nonablative treatment of concave skin irregularities such as atrophic acne scars.30 Unlike laser energy, RF energy is not absorbed by melanin, making this modality potentially safer in subjects with dark skin. Sublative rejuvenation technology attempts to blend ablative and nonablative modalities to create a more effective therapy with less downtime. As with all acne scarring treatments, the deepest and most "bound down" scars are the most difficult to treat. These scars have been treated in the past with punch elevation, excision, subcision, or a combination of these modalities. The bipolar RF device with diode laser is designed to remodel these scars without an epidermal wound by creating a coagulative focal point at 1.5mm where the RF and laser meet, stimulating collagen synthesis at the depth of the scar.²⁷



Figure 9. East Indian study patient before and one month after five treatments of SR and DLRF

As stated previously, acne scars have been successfully treated with nonablative and ablative fractional lasers. Prior evaluation of nonablative therapies showed modest success. 31-34 The development of the 1550nm Er:YAG laser was an important advance in the treatment of acne scarring by nonablative fractional photothermolysis 35 as well as for the treatment of darker skin. However, multiple treatment sessions are necessary to achieve 50- to 75-precent

improvement. Ablative lasers have also been successfully utilized in the hopes of reducing the number of treatments required.³⁶ One study showed that combining nonablative with ablative resurfacing produced a better result with fewer complications than ablative resurfacing alone.¹⁸ Another study³⁷ compared nonablative (fractional erbium glass) with ablative (fractional carbon dioxide) laser. The ablative laser produced better results after one session, but with considerably more

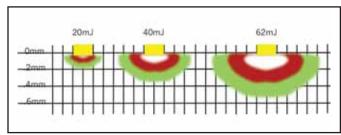


Figure 10. Thermal profile at different energies Sublative 64 (.86W/electrode). As the energy is increased, both the depth and diameter of affected tissue increases.

discomfort and downtime.

Additionally, safe and effective treatments for skin of color have become increasingly sought after, leading to usage of other modalities than light in order to avoid the frequent problem of postinflammatory hyperpigmentation. Trying to balance the social downtime, discomfort, efficacy, and safety of energy-based aesthetic treatments has been an important theme over the last 10 years. Sublative rejuvenation is a modality that attempts to answer these aesthetic needs in a different way by utilizing mainly RF and harnessing the novel concept of ablative RF, something that is used frequently in other areas of medicine.

Acne scars are principally dermal. The resurfacing, chemical peels, and diamond fraises of the past aimed to wound the epidermis and the superficial dermis profoundly and thus secondarily promote dermal remodeling. Nonablative erbium glass resurfacing or ablative fractional treatments can penetrate deeply into the dermis making this a more direct method, while promoting faster healing from the reservoir of untreated skin.38 These wounds tend to be straight columns into the dermis. whereas the sublative fractional bipolar RF current creates small epidermal wounds that are much wider in the dermis (Figure 10). The

advantage of this in relation to scarring is that the downtime is limited due to minimizing epidermal injury, yet the scar remodeling is still maximized due to the profound direct impact on the dermis. The DLRF combination has a focal point of about 1.5mm, where the laser and RF energies merge and create a focal coagulation at a deep level effect that is probably most important in the treatment of punched out, ice pick, or troughed scars. The nonablative dermal injuries create collagen remodeling that is delayed, mirroring the delayed results in the subjects of the present study.

The main advantages of the RF modalities are their lack of side effects, especially in darker skin, and the low social downtime. Although there is crusting for a number of days, it is relatively easy to cover with makeup. Even without makeup, the crusting is not significantly disfiguring. The RF modalities require multiple treatments and the treatments require time before results are seen due to the need for collagen regeneration, which takes 1 to 6 months. The platform used for this study was a prototype; the newer generations have energies that are more than twice the energies that were available to us at the time.

Conclusion

The combination of diode laser and bipolar RF energy along with sublative

bipolar RF is a safe and effective modality for the treatment of both superficial and deep acne scars. The encouraging results warrant additional studies to further characterize this modality.

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